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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,123	12/29/1998	ROBERT A. RAY	6328-21	3601

7590 06/22/2005  
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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/222,123

Applicant(s)

RAY ET AL.

Examiner

LaToya I. Cross

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1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-21, 24, 26, 27, 29-32, 34, 36-40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21, 24, 26, 27, 29-32, 34, 36-40 and 42-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 21, 2005 has been entered.

### ***Withdrawal of Rejections from Previous Office Action***

- The obviousness rejection over Levine in view of Jacke is withdrawn in view of Applicants' amendment to recite the presence of an extraction agent and that the pad is treated with an agent to aid in collection, preservation, separation, storage, transport, recovery or analysis of the sample.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 19, 21, 24-27, 29-32, 33, 36-40, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over European patent 583078 to Ostrup in view of European patent 494599 to Fujiura.

Ostrup discloses an apparatus for collecting and handling a sample. The apparatus comprises filter paper package, which has openings through which a sample is absorbed. The openings also allow pieces of the filter paper to be punched out of the filter paper package. Thus, the openings facilitate removal of a part of the filter paper. The pieces that are punched out are put into buffer solution and the sample is dissolved in the buffer solution for measurement. The outside of the filter paper package contains a bar code for identifying the sample and instructions for aiding the user in using the device.

Ostrup differs from the instantly claimed invention in that there is no disclosure of 1) urine samples being collected and 2) polyvinyl alcohol being used as the filter paper.

With respect to urine being collected, Ostrup teaches that the device is suitable for collecting biological samples that would normally be difficult to send in liquid form via Post Office mail to a laboratory. Ostrup teaches that using a device as disclosed would present a smaller risk of contacting infectious disease and trying to manipulate and handle a liquid sample. Therefore, it would have been obvious to one of ordinary

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skill in the art that the device of Ostrup would be suitable for urine samples, as well, since it would provide a means to collect and transport the sample with ease and without the danger of contacting infectious diseases that may be present in the sample.

With respect to the use of polyvinyl alcohol as the absorbent material, Fujiura teaches that gelling materials, such as polyvinyl alcohol have water-absorbent properties that would allow a liquid sample to gel, allowing for easier handling without the danger of spilling. Fujiura also teaches that the polyvinyl alcohol gels in a short period of time, which would alleviate any unwanted waiting times. Therefore, it would have been obvious to one of ordinary skill in the art to use a polyvinyl alcohol pad to collect the biological sample due to its absorbent properties and its ability to gel liquids quickly.

With respect to incorporating BVA into the collection pad, it is known that BVA serves a preserving agent for bodily fluids. It would have been obvious to one of ordinary skill in the art to incorporate BVA into the collection pad to aid in preserving the sample until time for analysis.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrup and Fujiura as applied to the claims above, and further in view of US Patent 5,976,895 to Cipkowski.

With respect to claim 20, neither Ostrup nor Fujiura teach a collection cup.

Cipkowski teaches a device for collecting and shipping body fluid samples. The device includes a cup ( 11). Test strips are inserted into the cup to contact the sample. It would have been obvious to one of ordinary skill in the art to use a cup with the collection strips of Ostrup as a means to deliver the sample to the test strip in a controlled manner and avoid spillage or waste of the sample.

#### *Response to Arguments*

5. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden  
Supervisory Patent Examiner  
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